K122413

5 510(k) Summary

SEP 13 2012

Submittal Date: September 7, 2012
Company Name: Forte Automation Systems, Inc.
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City, St, Zip: Machesney Park, IL 61115
Country: USA
Phone: +1 (815) 633-236 00
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Contact: Phil Reece
Contact Title: Regulatory Manager

Device Name:

Common Name:	Patient Positioning System
Device:	Couch, Radiation Therapy, Powered
Regulation Description:	Powered radiation therapy patient support assembly
Regulation Medical Specialty:	Radiology
Review Panel:	Radiology
Product Code:	JAI
Submission Type:	510(k)
Regulation Number:	892.5770
Device Class:	2

Device Description:

The patient positioning system is a SCARA designed robotic arm allowing six degrees of freedom.

Indications for Use:

The patient positioning system is a SCARA designed robotic arm designed to position a patient for medical procedures prescribed by oncologists and others that require a high degree of accuracy and repeatability.

Predicate Device:

A similar system has received Substantial Equivalence (SE) through Accuray Incorporated under number K042146 dated August 5, 2004.

Technolgical Characteristics:

The technological differences between the predicate and the submitted devices are as follows:

	Predicate Device	**Submitted Device**
Vertical travel	Ball screw driven	Rack and pinion driven
Axes 4, 5, and 6	Belt driven	Gear driven
Couch top coupling	Single couch top	Multiple couch tops
Measuring Patient weight	N/A	Load Cell

Figure 1 Predicate Differences

Theses changes are included in another patient positioning system device that was included as a part of different submittal K100766 with a different intended use.

Nonclinical Tests:

Electromagnetic compatibility and susceptibility tests as well as surge and static tests were performed by a third party on the submitted device and all passed. Vibration tests were performed by a third party on the submitted device and passed. Speed, accuracy and collision detection tests were performed by Forte Automation and passed.

Clinical Tests:

The submitted device does not impart energies into a patient. Therefore no clinical testing was needed.

Testing Conclusions:

Forte Automation has manufactured the predicate device as well as the submitted device. All of the tests performed on the submitted device were done to the industries normal criteria and passed proving the submitted device meets or exceeds the safety and effectiveness of both of the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 13 2012

Mr. Phil Reece
Regulatory Manager
Forte Automation Systems, Inc.
8155 Burden Road
MACHESNEY PARK IL 61115

Re: K122413
Trade/Device Name: Patient Positioning System (PPS)
Regulation Number: 21 CFR 892.5770
Regulation Name: Powered radiation therapy patient support assembly
Regulatory Class: II
Product Code: JAI
Dated: August 3, 2012
Received: August 8, 2012

Dear Mr. Reece:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number if Known:

~~Unknown~~ K122413

Device Name:

Patient Positioning System (PPS)

Indications for Use:

The patient positioning system is a SCARA designed robotic arm designed to position a patient for medical procedures prescribed by oncologists and others that require a high degree of accuracy and repeatability.

Prescription Use __X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
OIVD
510(k) K122413